MAY 0 7 2001 BE Actitioner's Docket No. U 015118-6

**PATENT** 

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Govindan RAJAMOHAN, et al Application No.: 10/814,850 Group No.: 1652

Filed: March 31, 2004 Examiner: Malgorzata A. Walicka

For: METHOD FOR OXYGEN REGULATED PRODUCTION OF RECOMBINANT

**STAPHYLOKINASE** 

Commissioner for Patents P. O. Box 1450 Alexandria, VA 22313-1450

### STATEMENT OF BIOLOGICAL CULTURE DEPOSIT

STATEMENT OF BIOLOGICAL COLICIAL DEI OST
Submission of a letter related to a biological deposit after a Notice of Alolwance may subject an application to a reduction in patent term adjustment under 37 C.F.R. 1.704(c)(10). See Notice of May 29, 2001, 1247 OG 111-112,
June 26, 2001.
CLIFFORD J. MASS
Name of Applicant or Assignee or Assignee's representative
CERTIFICATION UNDER 37 C.F.R. SECTIONS 1.8(a) and 1.10*
(When using Express Mail, the Express Mail label number is mandatory;
Express Mail certification is optional.)
fy that, on the date shown below, this correspondence is being:
MAILING
posited with the United States Postal Service in an envelope addressed to the Commissioner for Patents, P. O. x 1450, Alexandria, VA 22313-1450.

37 C.F.R. SECTION 1.8(a)

37 C.F.R. SECTION 1.10\*

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Signature

Date: April 30, 2007

□ CLIFFORD J MASS
(type or print name of person certifying)

\*WARNING:

Each paper or fee filed by "Express Mail" must have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C.F.R. section 1.10(b).

"Since the filing of correspondence under section 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable care, requests for waiver of this requirement will **not** be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.

pRM1	MTCC 5146
Strain	Accession number
pOXYSAK-1	MTCC 5147
Strain	Accession number
pOXYSAK-2	MTCC05148
Strain	Accession number
Strain	Accession number
2. That the date of the above deposit is:	
(check approp	priate item below)
[ ] after the U.S. filing date of this application	
the same culture(s) described in the app  That the name and address of the depository  MICROBIAL TYPE CULTURE COLLECTION  TECHNOLOGY	olication as filed is attached.  is:  I AND GENE BANK INSTITUTE OF MICROBIAL
the same culture(s) described in the app  That the name and address of the depository  MICROBIAL TYPE CULTURE COLLECTION  TECHNOLOGY	is:
the same culture(s) described in the app  That the name and address of the depository  MICROBIAL TYPE CULTURE COLLECTION  TECHNOLOGY  Name of SECTOR 39-A, CHANDIGARH - 160 036,	is:  I AND GENE BANK INSTITUTE OF MICROBIAL  of depository  INDAI
the same culture(s) described in the app  3. That the name and address of the depository  MICROBIAL TYPE CULTURE COLLECTION FECHNOLOGY  Name of SECTOR 39-A, CHANDIGARH - 160 036,	olication as filed is attached.  is:  NAND GENE BANK INSTITUTE OF MICROBIAL  of depository
the same culture(s) described in the app  That the name and address of the depository  MICROBIAL TYPE CULTURE COLLECTION  TECHNOLOGY  Name of SECTOR 39-A, CHANDIGARH - 160 036,  Address  That a statement that the culture(s) deposited was (were) capable of reproduction, if appropriate	olication as filed is attached.  is:  I AND GENE BANK INSTITUTE OF MICROBIAL of depository  INDAI of depository  with the above named depository was (were) viable and
the same culture(s) described in the app  3. That the name and address of the depository  MICROBIAL TYPE CULTURE COLLECTION FECHNOLOGY  Name of SECTOR 39-A, CHANDIGARH - 160 036, Address  4. That a statement that the culture(s) deposited was (were) capable of reproduction, if appropriate executed by:	olication as filed is attached. is:  I AND GENE BANK INSTITUTE OF MICROBIAL of depository  INDAI

hereby state:

WARNING: If the applicant himself or a competent third party makes the statement that the microorganism is viable and is capable of reproduction, if appropriate, then the tests must have been performed on a sample certified to have been (1) received by the depository with the same samples actually deposited and (2) promptly returned to applicant.

5. That, with respect to the permanence of the culture(s) deposit:
(complete a, b, or c)
<ul> <li>a. [X] the depository is an official depository, in accordance with the Budapest Treaty for the above deposited culture(s).</li> <li>b. [] the depository affords permanence of the deposit for at least 30 years or at least 5 years after the most recent storage request, whichever is longest.</li> <li>c. [] evidence that permanent availability of the microorganism is assured is provided in the form of the attached copy of the contract with the above-mentioned depository with respect to the deposited culture(s).</li> </ul>
I state that should the microorganism(s) mutate, become nonviable or be inadvertently destroyed, applicants will replace such microorganism(s) for at least 30 years from the date of the original deposit, or at least 5 years from the date of the most recent request for release of a sample or for the life of any patent issued on the above-mentioned application, whichever period is longer.
6. That, with respect to availability of the culture(s), I state that the deposit has been made under conditions of assurance of (a) ready accessibility thereto by the public if a patent is granted whereby all restrictions to the availability to the public of the culture so deposited will be irrevocably removed upon the granting of the patent (M.P.E.P. 608.01 (p)), and (b) access to the culture will be available during pendency of the patent application to one determined by the Commissioner to be entitled thereto under 37 C.F.R. section 1.14 and 35 U.S.C. section 122.
[ ] Evidence of the accessibility of the culture(s) as set forth above is provided in the form of the attached copy of the contract with the above mentioned depository with respect to the deposited cultures.
CLIFFORD J. MASS  (type or print name of person signing)

LADAS & PARRY LLP 26 WEST 61ST STREET NEW YORK, NEW YORK 10023 REG. NO.30,086(212)708-1890

Date

P.O. Address of Signatory

CLIFFORD J. MASS
(uppe or print name of person signing)

Signature

[ ] Assignee of complete interest [X] Person authorized to sign on behalf of assignee	
(complete the following, if a	applicable)
(type name of assignee)	
Address of assignee	
Title of person authorized to sign on behalf of assignee: Assignment recorded in PTO on Reel Frame	
A "STATEMENT UNDER 37 C.F.R. 3.73(b)" is attached.	

# BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

# INTERNATIONAL FORM

To

Sri G.Rajamohan Scientist Institute of Microbial Technology Sector – 39A Chandigarh – 160 036. INDIA

NAME AND ADDRESS OF THE DEPOSITOR

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT issued pursuant to Rule 7.1 by the INTERNATIONAL DEPOSITARY AUTHORITY Identified at the bottom of this page

I. IDENTIFICATION OF THE MICROORGANISM	
Identification reference given by the DEPOSITOR:	Accession number given by the INTERNATIONAL DEPOSITARY AUTHORITY:
E.coli pRM1	MTCC 5146
II. SCIENTIFIC DESCRIPTION AND/OR PROPOSED TAX	KONOMIC DESIGNATION
The microorganism identified under I above was accompanied by	
(X) a scientific description	
() a proposed taxonomic designation	
(Mark with a cross where applicable)	~
III. RECEIPT AND ACCEPTANCE	
This International Depositary Authority accepts the microorganism	m identified under above,
which was received by it on	(date of the original deposit)
IV. RECEIPT OF REQUEST FOR CONVERSION	
The microorganism identified under I above was received by this	International Depositary
Authority on 19.03.2002 (date of the	original deposit) and a request to convert the original
deposit under the Budapest Treaty was received by it on 25.03	3,2004 (date of receipt of request for conversion)
V. INTERNATIONAL DEPOSITARY AUTHORITY	
Name: Dr. G.S.PRASAD	MTCC-an IDA 95 ML-S
Address: Microbial Type Culture Collection & Gene Bank Institute of Microbial Technology Sector 39-A, Chandigarh - 160 036	Institute of Microbial Technology Signature (1) (1967) Signature (1967) Si
India	Date: 30.03.2004

Where Rule 6.4(d) applies, such date is the date on which the status of International Depositary Authority was acquired

<sup>\*</sup> Form MTCC BP/4 (sole page)

# BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

## INTERNATIONAL FORM

To

Sri G.Rajamohan Scientist Institute of Microbial Technology Sector – 39A Chandigarh – 160 036. INDIA

NAME AND ADDRESS OF THE PARTY TO WHOM THE VIABILITY STATEMENT IS ISSUED VIABILITY STATEMENT issued pursuant to Rule 10.2 by the INTERNATIONAL DEPOSITARY AUTHORITY Identified on the following page

I. DEPOSITOR	II. IDENTIFICATION OF THE MICROORGANISM
Name: Sri G.Rajamohan Address: Scientist Institute of Microbial Technology Sector – 39A	Accession number given by the INTERNATIONAL DEPOSITARY AUTHORITY  MTCC 5146  Date of the deposit or of the transfer: 30-03-2004

III. VIABILITY STATEMENT	
The viability of the microorganism identified under II a	bove was tested
on <u>29.03.2004</u>	<sup>2</sup> on that date, the said microorganism was
(X) viable	
no longer viable	

- Indicate the date of the original deposit or, where the new deposit or a transfer has been made, the most recent relevant date (date of the new deposit or date of the transfer).
- In the cases referred to in Rule 10.2(a)(ii) and (iii), refer to the most recent viability test.
- <sup>3</sup> Mark with a cross the applicable box

<sup>\*</sup> Form MTCC BP/9 (first page)

# V. INTERNATIONAL DEPOSITARY AUTHORITY Name: Dr. G.S. PRASAD Microbial Type Culture & Gene Bank Address: Institute of Microbial Technology Sector 39-A, Chandigarh - 160 036 India N. INTERNATIONAL DEPOSITARY AUTHORITY Signature of Coard hand the power to represent the International Microbial Technology official Sector 30-A, Chandigarh - 160 036 India Date: 30 · 0 3 · 2004

<sup>&</sup>lt;sup>4</sup> Fill in if the information has been requested and if the results of the test were negative.

<sup>†</sup> Form MTCC BP/9 (second and last page)

# BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

# INTERNATIONAL FORM

Sri G.Rajamohan Scientist Institute of Microbial Technology Sector - 39A Chandigarh - 160 036. INDIA

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT issued pursuant to Rule 7.1 by the
INTERNATIONAL DEPOSITARY AUTHORITY
Identified at the bottom of this page

NAME AND ADDRESS OF THE DEPOSITOR	
. IDENTIFICATION OF THE MICROORGANISM	
dentification reference given by the DEPOSITOR:	Accession number given by the INTERNATIONAL DEPOSITARY AUTHORITY:
E.coli pOXYSAK1	MTCC 5147
I. SCIENTIFIC DESCRIPTION AND/OR PROPOSED TAX	KONOMIC DESIGNATION
The microorganism identified under I above was accompanied by	
_	•
X) a scientific description	
) a proposed taxonomic designation	
Mark with a cross where applicable)	<b>~</b> ."
II. RECEIPT AND ACCEPTANCE	
This International Depositary Authority accepts the microorganism	m identified under I above,
which was received by it on	(date of the original deposit)
IV. RECEIPT OF REQUEST FOR CONVERSION	
The microorganism identified under I above was received by this	International Depositary
Authority on 19.03.2002 (date of the	original deposit) and a request to convert the original
deposit under the Budapest Treaty was received by it on 25.03	3,2004 (date of receipt of request for conversion)
V. INTERNATIONAL DEPOSITARY AUTHORITY	
Name: Dr. G.S.PRASAD	· G5/W_5
Address:	
Microbial Type Culture Collection & Gene Bank	Signature of the person of the power to represent the International Signature of the Internat
Institute of Microbial Technology	Sector 39-A, Chandigarh-160 036
Sector 39-A, Chandigarh - 160 036 India	Date: [NDIA 30.03.2004-
India	Pare HADIM 30.02.7004

<sup>\*</sup> Form MTCC BP/4 (sole page)

# BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

## INTERNATIONAL FORM

To

Sri G.Rajamohan Scientist Institute of Microbial Technology Sector – 39A Chandigarh – 160 036. INDIA

NAME AND ADDRESS OF THE PARTY TO WHOM THE VIABILITY STATEMENT IS ISSUED VIABILITY STATEMENT issued pursuant to Rule 10.2 by the INTERNATIONAL DEPOSITARY AUTHORITY Identified on the following page

I. DEPOSITOR	II. IDENTIFICATION OF THE MICROORGANISM
Name: Sri G.Rajamohan Address: Scientist Institute of Microbial Technology Sector – 39A Chandigarh – 160 036, INDIA	Accession number given by the INTERNATIONAL DEPOSITARY AUTHORITY  MTCC 5147  Date of the deposit or of the transfer:  30-03-2004

III. VIABILITY STATEMENT	
The viability of the microorganism identified under II above was tested	
on 29.03,2004	<sup>2</sup> on that date, the said microorganism was
	•
(X) viable	
CALL VIII.	
()³ no longer viable	

- Indicate the date of the original deposit or, where the new deposit or a transfer has been made, the most recent relevant date (date of the new deposit or date of the transfer).
- <sup>2</sup> In the cases referred to in Rule 10.2(a)(ii) and (iii), refer to the most recent viability test.
- Mark with a cross the applicable box

<sup>\*</sup> Form MTCC BP/9 (first page)

IV. CONDITIONS UNDER WHICH THE VIABILITY TEST HAS BEEN PERFORMED		
V. INTERNATIONAL DEPOSITARY AUTHORITY		
Name:  Dr. G.S. PRASAD  Microbial Type Culture & Gene Bank  Address: Institute of Microbial Technology Sector 39-A, Chandigarh - 160 036 India	Signatured of Contact and Date power to represent the International Process of Sector 39-A, Chandigarh-165 556 INDIA  Date: 20.03.2004	

<sup>&</sup>lt;sup>4</sup> Fill in if the information has been requested and if the results of the test were negative.

<sup>†</sup> Form MTCC BP/9 (second and last page)

# BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

## INTERNATIONAL FORM

Sri G.Rajamohan Scientist Institute of Microbial Technology Sector – 39A Chandigarh – 160 036. INDIA

NAME AND ADDRESS OF THE PARTY TO WHOM THE VIABILITY STATEMENT IS ISSUED

VIABILITY STATEMENT issued pursuant to Rule 10.2 by the INTERNATIONAL DEPOSITARY AUTHORITY Identified on the following page

1. DEPOSITOR	IL IDENTIFICATION OF THE MICROORGANISM
	Accession number given by the INTERNATIONAL DEPOSITARY AUTHORITY
Name:	INTERNATIONAL DEPOSITAR I AUTHORITT
Sri G.Rajamohan	
Address:	MTCC 5148
Scientist	
Institute of Microbial Technology	Date of the deposit or of the transfer:
<del></del>	•
Sector - 39A	30-03-2004
Chandigarh - 160 036 INDIA	•

III. VIABILITY STATEMENT	
The viability of the microorganism identified under II above was tested	
on <u>29.03.2004</u>	<sup>2</sup> on that date, the said microorganism was
(X) viable	
() <sup>3</sup> no longer viable	

Indicate the date of the original deposit or, where the new deposit or a transfer has been made, the most recent relevant date (date of the new deposit or date of the transfer).

<sup>&</sup>lt;sup>2</sup> In the cases referred to in Rule 10.2(a)(ii) and (iii), refer to the most recent viability test.

<sup>&</sup>lt;sup>3</sup> Mark with a cross the applicable box

<sup>\*</sup> Form MTCC BP/9 (first page)

IV. CONDITIONS UNDER WHICH THE VIABILITY TEST HAS BEEN PERFORMED <sup>4</sup>		
Name:	G5/W-5	
Dr. G.S. PRASAD	\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \	
Microbial Type Culture & Gene Bank	Signatur 10 Grant problem power to represent the International Depositary Authority or of authorised official 1915 ILLUIS OF MICCODIA! Jechnology	
Address:	Sector 39-A, Chandigarh-190 035	
Institute of Microbial Technology	INDIA	
Sector 39-A, Chandigarh - 160 036	Date: 30.03.2004	
India	30.03	

<sup>&</sup>lt;sup>4</sup> Fill in if the information has been requested and if the results of the test were negative.

<sup>&</sup>lt;sup>†</sup> Form MTCC BP/9 (second and last page)